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Attorneys for Defendant and Counterclaimant Hologenix, LLC

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

Multiple Energy Technologies, LLC

Plaintiff,

v.

Hologenix, LLC,

Defendants.

Hologenix, LLC

Counterclaimant,

v.

Multiple Energy Technologies, LLC

Counter-Defendant.

Case No. 2:19-cv-01483-PA-RAO

**DEFENDANT'S ANSWER TO
COMPLAINT AND
COUNTERCLAIM**

Complaint Filed: February 28, 2019
Counterclaim Filed: April 12, 2019

JURY TRIAL DEMANDED

1 Defendant and Counterclaimant Hologenix, LLC (“Defendant” or
2 “Hologenix”), by and through its undersigned counsel, hereby files its Answer to
3 the Complaint by Plaintiff Multiple Energy Technologies, LLC (“Plaintiff” or
4 “MET”) as well as its Counterclaim against Counter-Defendant MET as follows:

5 1. Answering paragraph 1 of the Complaint, Defendant admits that
6 Plaintiff purports to bring an action arising out of Defendant’s advertising and
7 promotion of material branded as Celliant® (“Celliant” or the “Product”).
8 Defendant denies the remaining allegations set forth in paragraph 1 of the
9 Complaint.

10 2. Answering paragraph 2 of the Complaint, Defendant affirmatively
11 alleges that the Product is a proprietary mix of safe, naturally occurring thermo-
12 reactive minerals selected for their unique properties and combined into a patented
13 formula. If Defendant’s proprietary blend of minerals is properly embedded into the
14 core of polyester fibers during the extrusion process, the resulting product has the
15 ability to absorb and re-emit the visible and infrared electromagnetic light energy
16 emitted by the body. These minerals then alter the wavelengths of this energy and
17 reflect them back to the body, making it possible for the tissue to absorb it. The
18 energy that the Product recycles back to the body has been proven to trigger
19 vasodilation in the capillary beds and make more oxygen available to cells, resulting
20 in more fuel for the body. Defendant lacks sufficient information to form a belief as
21 to the truth or falsity of the remaining allegations set forth in paragraph 2 of the
22 Complaint and therefore denies same.

23 3. Answering paragraph 3 of the Complaint, Defendant admits that
24 certain marketing and advertising materials state that the U.S. Food and Drug
25 Administration (“FDA”) determined Celliant products are medical devices and
26 general wellness products, as defined in Section 201(h) of the Federal Food, Drug
27 and, Cosmetic Act. Defendant further admits that, on rare occasions, it erroneously
28 noted that the Product was approved by the FDA and/or the media inaccurately

1 reported that the Product was approved by the FDA. Defendant affirmatively
2 alleges that the FDA determined Celliant products are medical devices and general
3 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
4 Cosmetic Act. Defendant also affirmatively alleges that its July 25, 2017 press
5 release speaks for itself. Defendant further affirmatively alleges that the Product
6 has been shown to increase local blood flow at the site of application in healthy
7 individuals. Defendant denies the remaining allegations set forth in paragraph 3 of
8 the Complaint.

9 4. Answering paragraph 4 of the Complaint, Defendant affirmatively
10 alleges that the FDA determined Celliant products are medical devices and general
11 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
12 Cosmetic Act. Defendant admits that the FDA has not “approved” the Product.
13 Defendant denies the remaining allegations in paragraph 4 of the Complaint.

14 5. Answering paragraph 5 of the Complaint, Defendant admits that its
15 marketing and advertising materials state that the FDA determined Celliant
16 products are medical devices and general wellness products, as defined in Section
17 201(h) of the Federal Food, Drug and, Cosmetic Act. Defendant further admits that
18 its advertising materials state that the Product can improve tissue oxygen, a process
19 vital to cells and muscles recovering through improved blood flow. Defendant
20 further admits that, on rare occasions, it erroneously noted that the Product was
21 approved by the FDA and/or the media inaccurately reported that the Product was
22 approved by the FDA. Defendant denies the remaining allegations set forth in
23 paragraph 5 of the Complaint.

24 6. Answering paragraph 6 of the Complaint, Defendant admits that its
25 marketing and advertising materials stated that the FDA determined Celliant
26 products are medical devices and general wellness products, as defined in Section
27 201(h) of the Federal Food, Drug and, Cosmetic Act. Defendant further admits that
28 its marketing and advertising materials state that Product can improve tissue

1 oxygen, a process vital to cells and muscles recovering through improved blood
 2 flow. Defendant also admits that its marketing and advertising materials state that
 3 improved tissue oxygen can increase performance, energy, strength and stamina,
 4 aids in faster recovery and promotes restful sleep. Defendant further admits that, on
 5 rare occasions, it erroneously noted that the Product was approved by the FDA
 6 and/or the media inaccurately reported that the Product was approved by the FDA.
 7 Defendant denies the remaining allegations set forth in paragraph 6 of the
 8 Complaint.

9 7. Defendant denies the allegations in paragraph 7 of the Complaint.

10 8. Defendant denies the allegations in paragraph 8 of the Complaint.

11 9. Defendant lacks sufficient information to form a belief as to the truth
 12 or falsity of the allegations set forth in paragraph 9 of the Complaint and therefore
 13 denies same.

14 **PARTIES**

15 10. Defendant lacks sufficient information to form a belief as to the truth
 16 or falsity of the remaining allegations set forth in paragraph 10 of the Complaint
 17 and therefore denies same.

18 11. Defendant lacks sufficient information to form a belief as to the truth
 19 or falsity of the remaining allegations set forth in paragraph 11 of the Complaint
 20 and therefore denies same.

21 12. Defendant lacks sufficient information to form a belief as to the truth
 22 or falsity of the remaining allegations set forth in paragraph 12 of the Complaint
 23 and therefore denies same.

24 13. Defendant lacks sufficient information to form a belief as to the truth
 25 or falsity of the remaining allegations set forth in paragraph 13 of the Complaint
 26 and therefore denies same.

27 14. Defendant admits the allegations in paragraph 14 of the Complaint.

15. Answering paragraph 15 of the Complaint, Defendant affirmatively alleges that the post on Celiant.com titled “*See How Celliant Is Made*” speaks for itself. Defendant admits that it sells the Product, both as a fiber and as a powder and that it sells the Product to Under Armour, Inc. affiliates. Except as expressly admitted herein, Defendant denies all remaining allegations set forth in paragraph 15 of the Complaint.

JURISDICTION AND VENUE

16. Answering paragraph 16 of the Complaint, Defendant does not dispute, at this time, that this Court has jurisdiction over it with respect to the claims asserted by Plaintiff.

17. Answering paragraph 17 of the Complaint, Defendant does not dispute, at this time, that venue is proper in this Court.

18. Answering paragraph 18 of the Complaint, Defendant admits that its headquarters are in Santa Monica, California. Defendant affirmatively alleges that the domicile of a limited liability company is based on the citizenship of its members. Defendant further affirmatively alleges that its members are citizens of California, Colorado, New York, Puerto Rico and the European Union. Except as expressly admitted herein, Defendant denies all remaining allegations set forth in paragraph 18 of the Complaint.

19. Defendant admits the allegations in paragraph 19 of the Complaint.

FACTUAL ALLEGATIONS

20. Answering paragraph 20 of the Complaint, Defendant admits that the Product is not “FDA-approved.” Defendant further admits that, on rare occasions, it erroneously noted that the Product was approved by the FDA and/or the media inaccurately reported that the Product was approved by the FDA. Defendant denies the remaining allegations in paragraph 20 of the Complaint.

21. Answering paragraph 21 of the Complaint, Defendant affirmatively alleges that the July 31, 2017 tweet and Facebook post on Celliant's accounts speak

1 for themselves. Except as expressly admitted herein, Defendant denies all
2 remaining allegations set forth in paragraph 21 of the Complaint.

3 22. Answering paragraph 22 of the Complaint, Defendant affirmatively
4 alleges that the August 10, 2017 tweet and Facebook post on Celliant's accounts
5 speak for themselves. Except as expressly admitted herein, Defendant denies all
6 remaining allegations set forth in paragraph 22 of the Complaint.

7 23. Answering paragraph 23 of the Complaint, Defendant affirmatively
8 alleges that the August 28, 2017 *Huffington Post* article by Vivien Moon titled "*The*
9 *Future of Health and Wellness Is a Responsive Textile*" speaks for itself. Except as
10 expressly admitted herein, Defendant denies all remaining allegations set forth in
11 paragraph 23 of the Complaint.

12 24. Answering paragraph 24 of the Complaint, Defendant admits that the
13 August 28, 2017 *Huffington Post* article by Vivien Moon titled "*The Future of*
14 *Health and Wellness Is a Responsive Textile*" was linked to its website. Except as
15 expressly admitted herein, Defendant denies all remaining allegations set forth in
16 paragraph 24 of the Complaint.

17 25. Answering paragraph 25 of the Complaint, Defendant affirmatively
18 alleges that the September 26, 2017 tweet on Celliant's account speaks for itself.
19 Except as expressly admitted herein, Defendant denies all remaining allegations set
20 forth in paragraph 25 of the Complaint.

21 26. Answering paragraph 26 of the Complaint Defendant affirmatively
22 alleges that the October 16, 2017 tweet and Facebook post on Celliant's accounts
23 speak for themselves. Except as expressly admitted herein, Defendant denies all
24 remaining allegations set forth in paragraph 26 of the Complaint.

25 27. Answering paragraph 27 of the Complaint, Defendant affirmatively
26 alleges that the February 22, 2018 article on Inc.com by Sonya Mann titled "*How to*
27 *Get E-Commerce Customers to Spend a Lot of Money at Once (and Then Do It*
28

1 *Again*)” speaks for itself. Except as expressly admitted herein, Defendant denies all
 2 remaining allegations set forth in paragraph 27 of the Complaint.

3 28. Answering paragraph 28 of the Complaint, Defendant affirmatively
 4 alleges that the June 27, 2018 article on Hunker.com by the “Hunker Team” titled
 5 “*7 Blankets That Do More Than Just Blanket*” speaks for itself. Except as
 6 expressly admitted herein, Defendant denies all remaining allegations set forth in
 7 paragraph 28 of the Complaint.

8 29. Answering paragraph 29 of the Complaint, Defendant affirmatively
 9 alleges that the July 18, 2018 article on Shape.com by Macaela Mackenzie titled
 10 “*This New Under Armour Athleisure Collection Is All About Recovery*” speaks for
 11 itself. Except as expressly admitted herein, Defendant denies all remaining
 12 allegations set forth in paragraph 29 of the Complaint.

13 30. Answering paragraph 30 of the Complaint, Defendant affirmatively
 14 alleges that the July 18, 2018 article on WWD Digital Daily by Jean Palmieri titled
 15 “*Après Workout*” speaks for itself. Except as expressly admitted herein, Defendant
 16 denies all remaining allegations set forth in paragraph 30 of the Complaint.

17 31. Answering paragraph 31 of the Complaint, Defendant affirmatively
 18 alleges that the August 27, 2018 article in Gear Patrol by an unidentified author and
 19 titled “*This Material You’ve Never Heard of Is Taking Over Activewear*” speaks for
 20 itself. Except as expressly admitted herein, Defendant denies all remaining
 21 allegations set forth paragraph in 31 of the Complaint.

22 32. Answering paragraph 32 of the Complaint, Defendant affirmatively
 23 alleges that the August 31, 2018 article on talkingpointsmemo.com titled “*Wrap*
 24 *Yourself In Wellness With This Infinity Blanket*” speaks for itself. Except as
 25 expressly admitted herein, Defendant denies all remaining allegations set forth in
 26 paragraph 32 of the Complaint.

27 33. Answering paragraph 33 of the Complaint, Defendant affirmatively
 28 alleges that the article on Mattress Clarity by Joe Auer titled “*How Does Celliant*

1 *Work?*” speaks for itself. Except as expressly admitted herein, Defendant denies all
2 remaining allegations set forth paragraph in 33 of the Complaint.

3 34. Answering paragraph 34 of the Complaint, Defendant denies that the
4 product listing at <https://www.pillows.com/purecare-celliant-queen-.html> currently
5 includes a specification stating it is FDA approved. Except as expressly admitted
6 herein, Defendant denies all remaining allegations set forth in paragraph 34 of the
7 Complaint.

8 35. Answering paragraph 35 of the Complaint, Defendant lacks sufficient
9 information to form a belief as to the intent of statements by third-parties regarding
10 the Product and therefore denies the same. Except as expressly admitted herein,
11 Defendant denies all remaining allegations set forth in paragraph 35 of the
12 Complaint.

13 36. Answering paragraph 36 of the Complaint, Defendant admits that it
14 uses the phrases “FDA-determined” to describe the Product. Defendant denies all
15 remaining allegations set forth in paragraph 36 of the Complaint.

16 37. Answering paragraph 37 of the Complaint, Defendant affirmatively
17 alleges that its July 25, 2017 press release speaks for itself. Except as expressly
18 admitted herein, Defendant denies all remaining allegations set forth paragraph 37
19 of the Complaint.

20 38. Answering paragraph 38 of the Complaint, Defendant affirmatively
21 alleges that its July 25, 2017 post on Celliant’s Facebook page speaks for itself.
22 Except as expressly admitted herein, Defendant denies all remaining allegations set
23 forth paragraph 38 of the Complaint.

24 39. Answering paragraph 39 of the Complaint, Defendant admits that it
25 has stated on Celliant’s website and on Celliant’s social media pages that the
26 Product is “FDA-determined.” Defendant denies all remaining allegations set forth
27 paragraph 39 of the Complaint.

28 40. Defendant admits the allegations in paragraph 40 of the Complaint.

1 41. Defendant admits the allegations in paragraph 41 of the Complaint.

2 42. Defendant admits the allegations in paragraph 42 of the Complaint.

3 43. Defendant admits the allegations in paragraph 43 of the Complaint.

4 44. Answering paragraph 44 of the Complaint, Defendant admits that it
5 posted a link to the article titled “REVOLUTIONARY COTTON-RICH YOGA
6 WEAR REDUCES RECOVERY TIME WITH FDA-DETERMINED MEDICAL
7 DEVICE CELLIANT TECHNOLOGY DEBUTS AT PREMIÈRE VISION
8 SHOW” that first appeared on the cottonusa.org website on Celliant’s website.
9 Defendant denies all remaining allegations set forth paragraph 44 of the Complaint.

10 45. Answering paragraph 45 of the Complaint, Defendant affirmatively
11 alleges that Draper Therapies’ July 28, 2017 press release speaks for itself. Except
12 as expressly admitted herein, Defendant denies all remaining allegations set forth
13 paragraph 45 of the Complaint.

14 46. Answering paragraph 46 of the Complaint, Defendant affirmatively
15 alleges that Bear Mattress’ 2017 press release speaks for itself. Except as expressly
16 admitted herein, Defendant denies all remaining allegations set forth paragraph 46
17 of the Complaint.

18 47. Answering paragraph 47 of the Complaint, Defendant affirmatively
19 alleges that the post on sleepopolis.com titled “*What is Celliant Fiber?*” speaks for
20 itself. Defendant admits that it posted a link to the post on sleepopolis.com titled
21 “*What is Celliant Fiber?*” on Celliant’s twitter account on or around November 4,
22 2017. Except as expressly admitted herein, Defendant denies all remaining
23 allegations set forth paragraph 47 of the Complaint.

24 48. Answering paragraph 48 of the Complaint, Defendant affirmatively
25 alleges that the post on fastcompany.com titled “*These high-tech pajamas are*
26 *proven to help your post-workout recovery?*” speaks for itself. Defendant admits
27 that it posted a link to the post on fastcompany.com titled “*These high-tech pajamas*
28 *are proven to help your post-workout recovery?*” on Celliant’s twitter account on or

1 around April 14, 2018. Except as expressly admitted herein, Defendant denies all
2 remaining allegations set forth paragraph 48 of the Complaint.

3 49. Answering paragraph 49 of the Complaint, Defendant affirmatively
4 alleges that the FDA determined Celliant products are medical devices and general
5 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
6 Cosmetic Act. Defendant admits that it shared a link to CF Stinson's June 11, 2018
7 Facebook post to Celliant's Facebook page. Defendant affirmatively alleges that
8 the June 11, 2018 Facebook post by CF Stinson speaks for itself. Except as
9 expressly admitted herein, Defendant denies all remaining allegations set forth
10 paragraph 49 of the Complaint.

11 50. Answering paragraph 50 of the Complaint, Defendant affirmatively
12 alleges that the FDA determined Celliant products are medical devices and general
13 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
14 Cosmetic Act. Defendant admits that it linked an October 12, 2018 article titled
15 "*Under Armour: 'We make people better'*" by Grace Whelan from
16 www.drapersonline.com to its website. Defendant affirmatively alleges that the
17 October 12, 2018 article titled "*Under Armour: 'We make people better'*" by Grace
18 Whelan speaks for itself. Except as expressly admitted herein, Defendant denies all
19 remaining allegations set forth paragraph 50 of the Complaint.

20 51. Answering paragraph 51 of the Complaint, Defendant affirmatively
21 alleges that the October 28, 2018 Facebook post on Celliant's account speaks for
22 itself. Except as expressly admitted herein, Defendant denies all remaining
23 allegations set forth in paragraph 51 of the Complaint.

24 52. Answering paragraph 52 of the Complaint, Defendant affirmatively
25 alleges that the FDA determined Celliant products are medical devices and general
26 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
27 Cosmetic Act. Defendant admits that the product listing at
28 <https://www.walmart.com/ip/Bare-Ultrawarmth-3mm-Scuba-Diving-Dive->

1 [Snorkeling-Gloves/531019045](#) states that “Celliant is scientifically proven and
2 FDA-determined.” Except as expressly admitted herein, Defendant denies all
3 remaining allegations set forth paragraph 52 of the Complaint.

4 53. Answering paragraph 53 of the Complaint, Defendant affirmatively
5 alleges that the FDA determined Celliant products are medical devices and general
6 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
7 Cosmetic Act. Defendant admits that the product listing at
8 [https://www.underarmour.com/en-us/mens-athlete-recovery-compression-](https://www.underarmour.com/en-us/mens-athlete-recovery-compression-leggings/pid1318387-001)
9 [leggings/pid1318387-001](https://www.underarmour.com/en-us/mens-athlete-recovery-compression-leggings/pid1318387-001) states that “Products powered by Celliant have been
10 determined by the FDA to increase localized circulation, leading to faster
11 recovery.” Except as expressly admitted herein, Defendant denies all remaining
12 allegations set forth paragraph 53 of the Complaint.

13 54. Defendant denies the allegations in paragraph 54 of the Complaint.

14 55. Answering paragraph 55 of the Complaint, Defendant admits that the
15 Product is not registered as a medical device with the FDA. Defendant
16 affirmatively alleges that the FDA determined Celliant products are medical
17 devices and general wellness products, as defined in Section 201(h) of the Federal
18 Food, Drug and, Cosmetic Act and that the FDA expressly stated that it does not
19 intend to enforce any applicable regulatory requirements for the Products under the
20 Federal Food, Drug, and Cosmetic Act and its implementing regulations, which
21 requirements include medical device establishment registration, product listing, and
22 premarket notification requirements. Except as expressly admitted herein,
23 Defendant denies all remaining allegations set forth paragraph 55 of the Complaint.

24 56. Answering paragraph 56 of the Complaint, Defendant affirmatively
25 alleges that the FDA determined Celliant products are medical devices and general
26 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
27 Cosmetic Act. Defendant further affirmatively alleges that in the course of its
28 interaction with FDA leading to FDA’s determination that the Celliant products are

1 medical devices and general wellness products, the scope of claims to be made for
2 Celliant-containing products was made known to FDA and feedback was obtained
3 on permitted and non-permitted claims. Except as expressly admitted herein,
4 Defendant denies all remaining allegations set forth paragraph 56 of the Complaint.

5 57. Answering paragraph 57 of the Complaint, Defendant affirmatively
6 alleges that the FDA determined Celliant products are medical devices and general
7 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
8 Cosmetic Act. Defendant further affirmatively alleges that in the course of its
9 interaction with FDA leading to FDA's determination that the Celliant products are
10 medical devices and general wellness products, the scope of claims to be made for
11 Celliant-containing products was made known to FDA and feedback was obtained
12 on permitted and non-permitted claims. Except as expressly admitted herein,
13 Defendant denies all remaining allegations set forth paragraph 57 of the Complaint.

14 58. Answering paragraph 58 of the Complaint, Defendant denies it has
15 engaged in false and deceptive advertising regarding the Product, that it has
16 obtained "ill-gotten gains" or that it has committed any unlawful act. Defendant
17 lacks sufficient information to form a belief as to the truth or falsity of the
18 allegations set forth in paragraph 58 of the Complaint regarding Plaintiff's
19 motivation for bringing this action and therefore denies same. Defendant denies the
20 remaining allegations of paragraph 58 of the Complaint.

21 59. Answering paragraph 59 of the Complaint, Defendant affirmatively
22 alleges that the FDA determined Celliant products are medical devices and general
23 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
24 Cosmetic Act. Defendant further admits that, on rare occasions, it erroneously
25 noted that the Product was approved by the FDA and/or the media inaccurately
26 reported that the Product was approved by the FDA. Except as expressly admitted
27 herein, Defendant denies all remaining allegations set forth paragraph 59 of the
28 Complaint.

1 60. Answering paragraph 60 of the Complaint, Defendant affirmatively
2 alleges that the FDA determined Celliant products are medical devices and general
3 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
4 Cosmetic Act and that the FDA expressly stated that the Product was not required
5 to be registered as a medical device with the FDA. Except as expressly admitted
6 herein, Defendant denies all remaining allegations set forth paragraph 60 of the
7 Complaint.

8 61. Answering paragraph 61 of the Complaint, Defendant admits that the
9 Product is not listed on the FDA's list of approved medical devices. Defendant
10 affirmatively alleges that the FDA determined Celliant products are medical
11 devices and general wellness products, as defined in Section 201(h) of the Federal
12 Food, Drug and, Cosmetic Act and that the FDA expressly stated it does not intend
13 to enforce any applicable regulatory requirements for the Products under the
14 Federal Food, Drug, and Cosmetic Act and its implementing regulations, which
15 requirements include product listing. Except as expressly admitted herein,
16 Defendant denies all remaining allegations set forth paragraph 61 of the Complaint.

17 62. Answering paragraph 62 of the Complaint, Defendant admits that the
18 Product is not registered as a medical device with the FDA. Defendant
19 affirmatively alleges that the FDA determined Celliant products are medical
20 devices and general wellness products, as defined in Section 201(h) of the Federal
21 Food, Drug and, Cosmetic Act and that the FDA expressly stated that it does not
22 intend to enforce any applicable regulatory requirements for the Products under the
23 Federal Food, Drug, and Cosmetic Act and its implementing regulations, which
24 requirements include medical device establishment registration, product listing, and
25 premarket notification requirements. Except as expressly admitted herein,
26 Defendant denies all remaining allegations set forth paragraph 62 of the Complaint.

1 63. Paragraph 63 of the Complaint asserts legal conclusions to which no
2 response is required. To the extent any response is required, Defendant denies the
3 allegations of paragraph 63 of the Complaint.

4 64. Paragraph 64 of the Complaint asserts legal conclusions to which no
5 response is required.

6 65. Defendant admits the allegations in paragraph 65 of the Complaint.

7 66. Paragraph 66 of the Complaint asserts legal conclusions to which no
8 response is required. To the extent any response is required, Defendant denies the
9 allegations of paragraph 66 of the Complaint.

10 67. Paragraph 67 of the Complaint asserts legal conclusions to which no
11 response is required. To the extent any response is required, Defendant denies the
12 allegations of paragraph 67 of the Complaint.

13 68. Defendant admits the allegations in paragraph 68 of the Complaint.

14 69. Answering paragraph 69 of the Complaint, Defendant affirmatively
15 alleges that the articles published by the GAO and FDA identified in paragraph 69
16 of the Complaint speaks for themselves. Except as expressly admitted herein,
17 Defendant denies all remaining allegations set forth paragraph 69 of the Complaint.

18 70. Answering paragraph 70 of the Complaint, Defendant affirmatively
19 alleges that the FDA determined Celliant products are medical devices and general
20 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
21 Cosmetic Act. Defendant further admits that, on rare occasions, it erroneously
22 noted that the Product was approved by the FDA and/or the media inaccurately
23 reported that the Product was approved by the FDA. Except as expressly admitted
24 herein, Defendant denies all remaining allegations set forth paragraph 70 of the
25 Complaint.

26 71. Answering paragraph 71 of the Complaint, Defendant affirmatively
27 alleges that the FDA determined Celliant products are medical devices and general
28 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,

1 Cosmetic Act. Defendant admits that the FDA did not “approve” the Product.
2 Except as expressly admitted herein, Defendant denies all remaining allegations set
3 forth paragraph 71 of the Complaint.

4 72. Answering paragraph 72 of the Complaint, Defendant affirmatively
5 alleges that the FDA determined Celliant products are medical devices and general
6 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
7 Cosmetic Act. Defendant further affirmatively alleges that the FDA does not
8 require premarket review of marketing claims for general wellness products or for
9 non-prescription medical devices. Defendant further affirmatively alleges that in
10 the course of its interaction with FDA leading to FDA’s determination that the
11 Celliant products are medical devices and general wellness products, the scope of
12 claims to be made for Celliant-containing products was made known to the FDA
13 and feedback was obtained on permitted and non-permitted claims. Defendant
14 lacks sufficient information to form a belief as to the truth or falsity of the
15 remaining allegations set forth in paragraph 72 and therefore denies same.

16 73. Paragraph 73 of the Complaint asserts legal conclusions to which no
17 response is required. To the extent any response is required, Defendant denies the
18 allegations of paragraph 73 of the Complaint.

19 74. Answering paragraph 74 of the Complaint, Defendant affirmatively
20 alleges that the FDA determined Celliant products are medical devices and general
21 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
22 Cosmetic Act. Except as expressly admitted herein, Defendant denies all remaining
23 allegations set forth paragraph 74 of the Complaint.

24 75. Answering paragraph 75 of the Complaint, Defendant affirmatively
25 alleges that the FDA determined Celliant products are medical devices and general
26 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
27 Cosmetic Act. Defendant further affirmatively alleges that the FDA does not
28 require premarket review of marketing claims for general wellness products or for

1 non-prescription medical devices. Defendant further affirmatively alleges that in
2 the course of its interaction with FDA leading to FDA's determination that the
3 Celliant products are medical devices and general wellness products, the scope of
4 claims to be made for Celliant-containing products was made known to FDA and
5 feedback was obtained on permitted and non-permitted claims. Except as expressly
6 admitted herein, Defendant denies all remaining allegations set forth paragraph 75
7 of the Complaint.

8 76. Answering paragraph 76 of the Complaint, Defendant affirmatively
9 alleges that the FDA determined Celliant products are medical devices and general
10 wellness products, as defined in Section 201(h) of the Federal Food, Drug and,
11 Cosmetic Act. Defendant denies the remaining allegations in paragraph 76 of the
12 Complaint.

13 77. Defendant denies the allegations in paragraph 77 of the Complaint.

14 78. Defendant denies the allegations in paragraph 78 of the Complaint.

15 79. Defendant denies the allegations in paragraph 79 of the Complaint.

16 80. Defendant denies the allegations in paragraph 80 of the Complaint.

17 81. Answering paragraph 81 of the Complaint, Defendant admits that it
18 makes claims about the health benefits of the Product, including that tests establish
19 that the Product can promote general wellness. Except as expressly admitted
20 herein, Defendant denies all remaining allegations set forth in paragraph 81 of the
21 Complaint

22 82. Answering paragraph 82 of the Complaint, Defendant affirmatively
23 alleges that its July 25, 2017 press release speaks for itself. Except as expressly
24 admitted herein, Defendant denies all remaining allegations set forth paragraph 82
25 of the Complaint.

26 83. Answering paragraph 83 of the Complaint, Defendant affirmatively
27 alleges that its October 28, 2018 Facebook post speaks for itself. Except as
28

1 expressly admitted herein, Defendant denies all remaining allegations set forth
2 paragraph 83 of the Complaint.

3 84. Defendant denies the allegations in paragraph 84 of the Complaint.

4 85. Paragraph 85 of the Complaint asserts legal conclusions to which no
5 response is required. To the extent any response is required, Defendant admits that
6 MET and Hologenix both promote and sell bioceramic material.

7 86. Defendant admits the allegations in paragraph 86 of the Complaint.

8 87. Answering paragraph 87 of the Complaint, Defendant denies that it
9 engaged in a campaign of false and misleading statements. Defendant lacks
10 sufficient information to form a belief as to the truth or falsity of the allegations set
11 forth in paragraph 87 of the Complaint regarding Plaintiff's purported relationships
12 with Under Armour, Inc. or American Textile Company (and specific timing
13 thereof) and therefore denies the same. Defendant denies any remaining allegations
14 of paragraph 87 of the Complaint.

15 88. Defendant lacks sufficient information to form a belief as to the truth
16 or falsity of the allegations set forth in paragraph 88 of the Complaint and therefore
17 denies same. Defendant denies any remaining allegations of paragraph 88 of the
18 Complaint.

19 89. Defendant lacks sufficient information to form a belief as to the truth
20 or falsity of the allegations set forth in paragraph 89 and therefore denies same.
21 Defendant denies any remaining allegations of paragraph 89 of the Complaint.

22 90. Answering paragraph 90 of the Complaint, Defendant admits that on
23 January 7, 2017 it posted a link from Time.com titled "*Under Armour Wants You to*
24 *Buy Tom Brady's Pajamas*" to Celliant's twitter account. Defendant lacks
25 sufficient information to form a belief as to the truth or falsity of the remaining
26 allegations set forth in paragraph 90 and therefore denies same.

27 91. Answering paragraph 91 of the Complaint, Defendant admits that on
28 April 24, 2017 it posted a link from sleepsherpa.com titled "*Tom Brady Pajamas*

1 *Review: Under Armor's New Performance Sleepwear*" to Celliant's twitter account.
2 Defendant denies the remaining allegations in paragraph 91 of the Complaint.

3 92. Defendant lacks sufficient information to form a belief as to the truth
4 or falsity of the allegations set forth in paragraph 92 and therefore denies same.
5 Defendant denies any remaining allegations of paragraph 92 of the Complaint.

6 93. Defendant denies the allegations in paragraph 93 of the Complaint.

7 94. Defendant lacks sufficient information to form a belief as to the truth
8 or falsity of the allegations set forth in paragraph 94 regarding statements made
9 during the purported contract negotiations between Plaintiff and Under Armour and
10 therefore denies same. Defendant denies any remaining allegations of paragraph 94
11 of the Complaint.

12 95. Defendant lacks sufficient information to form a belief as to the truth
13 or falsity of the allegations set forth in paragraph 95 and therefore denies same.
14 Defendant denies any remaining allegations of paragraph 95 of the Complaint.

15 96. Defendant lacks sufficient information to form a belief as to the truth
16 or falsity of the allegations set forth in paragraph 96 and therefore denies same.
17 Defendant denies any remaining allegations of paragraph 96 of the Complaint.

18 97. Answering paragraph 97 of the Complaint, Defendant admits that it
19 entered into a contract with Under Armour to supply the Product. The terms of the
20 contract speak for themselves. Defendant denies any remaining allegations in
21 paragraph 97 of the Complaint.

22 98. Answering paragraph 98 of the Complaint, Defendant affirmatively
23 alleges that its July 25, 2017 press release speaks for itself. Except as expressly
24 admitted herein, Defendant denies all remaining allegations set forth paragraph 98
25 of the Complaint. Defendant further admits that, on rare occasions, it erroneously
26 noted that the Product was approved by the FDA and/or the media inaccurately
27 reported that the Product was approved by the FDA. Except as expressly admitted
28

1 herein, Defendant denies all remaining allegations set forth in paragraph 98 of the
2 Complaint.

3 99. Defendant lacks sufficient information to form a belief as to the truth
4 or falsity of the allegations set forth in paragraph 99 and therefore denies same.
5 Defendant denies any remaining allegations of paragraph 99 of the Complaint.

6 100. Answering paragraph 100 of the Complaint, Defendant admits that it
7 entered into a contract with Under Armour to supply the Product. The terms of the
8 contract speak for themselves. Defendant lacks sufficient information to form a
9 belief as to the truth or falsity of the allegations regarding Plaintiff's knowledge.
10 Defendant denies any remaining allegations in paragraph 100 of the Complaint.

11 101. Defendant denies the allegations in paragraph 101 of the Complaint.

12 102. Answering paragraph 102 of the Complaint, Defendant admits that it
13 entered into a contract with Under Armour to supply the Product. The terms of the
14 contract speak for themselves. Defendant denies any remaining allegations in
15 paragraph 102 of the Complaint.

16 103. Defendant lacks sufficient information to form a belief as to the truth
17 or falsity of the allegations set forth in paragraph 103 and therefore denies same.
18 Defendant denies any remaining allegations of paragraph 103 of the Complaint.

19 104. Answering paragraph 104 of the Complaint, Defendant admits that
20 promotes Under Armour's product on Cellaint.com. Defendant denies the
21 remaining allegations in paragraph 104 of the Complaint.

22 105. Defendant denies the allegations in paragraph 105 of the Complaint.

23 106. Answering paragraph 106 of the Complaint, Defendant admits that
24 American Textile makes bedding. Defendant lacks sufficient information to form a
25 belief as to the truth or falsity of the remaining allegations set forth in paragraph
26 106 and therefore denies same.

27 107. Defendant lacks sufficient information to form a belief as to the truth
28 or falsity of the allegations set forth in paragraph 107 and therefore denies same.

1 120. Paragraph 120 of the Complaint asserts legal conclusions to which no
2 response is required. It is also unclear which specific statements Plaintiff is referring
3 to in this paragraph. To the extent any response is required, Defendant denies the
4 allegations of paragraph 120 of the Complaint.

5 121. Paragraph 121 of the Complaint asserts legal conclusions to which no
6 response is required. It is also unclear which specific statements Plaintiff is referring
7 to in this paragraph. To the extent any response is required, Defendant denies the
8 allegations in paragraph 121 of the Complaint.

9 122. Paragraph 122 of the Complaint asserts legal conclusions to which no
10 response is required. It is also unclear which specific statements Plaintiff is referring
11 to in this paragraph. Defendant also lacks sufficient information to form a belief as
12 to the truth or falsity of the allegations set forth in paragraph 122 of the Complaint
13 and therefore denies same.

14 123. Paragraph 123 of the Complaint asserts legal conclusions to which no
15 response is required. To the extent any response is required, Defendant denies the
16 allegations in paragraph 123 of the Complaint.

17 124. Paragraph 124 of the Complaint asserts legal conclusions to which no
18 response is required. To the extent any response is required, Defendant denies the
19 allegations in paragraph 124 of the Complaint.

20 125. Paragraph 125 of the Complaint asserts legal conclusions to which no
21 response is required. To the extent any response is required, Defendant denies the
22 allegations in paragraph 125 of the Complaint.

23 126. Paragraph 126 of the Complaint asserts legal conclusions to which no
24 response is required. To the extent any response is required, Defendant denies the
25 allegations in paragraph 126 of the Complaint.

26 127. Paragraph 127 of the Complaint asserts legal conclusions to which no
27 response is required. To the extent any response is required, Defendant denies the
28 allegations in paragraph 127 of the Complaint.

1 herein, Defendant denies all remaining allegations set forth in paragraph 136 of the
2 Complaint.

3 137. Defendant lacks sufficient information to form a belief as to the truth
4 or falsity of the allegations set forth in paragraph 137 of the Complaint and
5 therefore denies same.

6 138. Defendant lacks sufficient information to form a belief as to the truth
7 or falsity of the allegations set forth in paragraph 138 of the Complaint and
8 therefore denies same.

9 139. Paragraph 139 of the Complaint asserts legal conclusions to which no
10 response is required. To the extent any response is required, Defendant denies the
11 allegations in paragraph 139 of the Complaint.

12 140. Paragraph 140 of the Complaint asserts legal conclusions to which no
13 response is required. To the extent any response is required, Defendant denies the
14 allegations in paragraph 140 of the Complaint.

15 141. Defendant lacks sufficient information to form a belief as to the truth
16 or falsity of the allegations set forth in paragraph 141 of the Complaint and
17 therefore denies same.

18 142. Defendant lacks sufficient information to form a belief as to the truth
19 or falsity of the allegations set forth in paragraph 142 of the Complaint and
20 therefore denies same.

21 143. Paragraph 143 of the Complaint asserts legal conclusions to which no
22 response is required. To the extent any response is required, Defendant lacks
23 sufficient information to form a belief as to the truth or falsity of the allegations set
24 forth in paragraph 143 of the Complaint and therefore denies same.

25 144. Paragraph 144 of the Complaint asserts legal conclusions to which no
26 response is required. To the extent any response is required, Defendant denies the
27 allegations in paragraph 144 of the Complaint.

1 **AFFIRMATIVE DEFENSES**

2 As for its affirmative defenses to all causes of action purported to be set forth
3 in Plaintiff's Complaint, Defendant alleges as follows. The Complaint does not
4 describe the claims against Defendant with sufficient particularity to enable
5 Defendant to determine what additional defenses it may have. Accordingly,
6 Defendant reserves the right to amend this Answer as appropriate and to assert all
7 additional defenses once the claims and/or facts become clear.

8 **FIRST AFFIRMATIVE DEFENSE**

9 **(Failure to State Cause of Action)**

10 Each and every purported cause of action of the Complaint alleged against
11 Defendant fails to state facts sufficient to constitute a cause of action against it.

12 **SECOND AFFIRMATIVE DEFENSE**

13 **(Unclean Hands)**

14 Plaintiff's claims are barred, in whole or in part, by the doctrine of unclean
15 hands.

16 **THIRD AFFIRMATIVE DEFENSE**

17 **(Estoppel)**

18 Plaintiff's claims are barred, in whole or in part, by the doctrine of estoppel.

19 **FOURTH AFFIRMATIVE DEFENSE**

20 **(Laches)**

21 Plaintiff's claims are barred, in whole or in part, by the doctrine of laches.

22 **FIFTH AFFIRMATIVE DEFENSE**

23 **(Waiver)**

24 Plaintiff's claims are barred, in whole or in part, by the equitable doctrine of
25 waiver.

1 **SIXTH AFFIRMATIVE DEFENSE**

2 **(No Duty)**

3 Plaintiff's third cause of action for negligent interference with prospective
4 economic advantage is barred, in whole or in part, by the fact that Defendant does
5 not owe Plaintiff any legal duty.

6 **SEVENTH AFFIRMATIVE DEFENSE**

7 **(Acts of Third Parties and/or Plaintiff)**

8 If Plaintiff did sustain any damages as alleged in the Complaint, that
9 damage, injury or loss, if any, was proximately caused or contributed to, in whole
10 or in part, by the conduct of Plaintiff, or other persons or entities (whether or not a
11 party to this lawsuit) other than Defendant.

12 **EIGHTH AFFIRMATIVE DEFENSE**

13 **(Causation)**

14 Defendant is not liable to Plaintiff, in whole or in part, because any losses that
15 Plaintiff allegedly suffered because none of the conduct attributed to Defendant
16 proximately caused the injuries alleged, and any such causation was superseded by
17 the conduct of Plaintiff and/or third parties and/or circumstances beyond the control
18 of Defendant, thus barring or diminishing any recovery against Defendant.

19 **NINTH AFFIRMATIVE DEFENSE**

20 **(Adequate Remedy)**

21 The Complaint, its causes of action, and its remedies for injunctive relief and
22 restitution are barred in light of the fact that Plaintiff has a legal remedy,
23 specifically money damages. Further, Plaintiff is not entitled to equitable relief
24 that duplicates any legal relief it may receive.

TENTH AFFIRMATIVE DEFENSE

(Failure to Mitigate)

Plaintiff failed to mitigate any purported damages. As such, any recovery by Plaintiff must be diminished by the amount of damages they could have reduced if it timely and appropriately acted to mitigate damages.

ELEVENTH AFFIRMATIVE DEFENSE

(Standing)

Plaintiff's claims are barred, in whole or in part, because it lacks standing to pursue the allegations in the Complaint.

TWELFTH AFFIRMATIVE DEFENSE

(Setoff)

Plaintiff's purported damages, if any, must be setoff by any damages caused by Plaintiff.

Defendant reserves the right to add such further defenses as may be warranted by the information developed through discovery.

PRAYER

WHEREFORE, having fully answered the Complaint, Defendant respectfully prays as follows:

- A. That Plaintiff takes nothing by way of its Complaint;
- B. That judgment be entered in favor of Defendant and against Plaintiff on the Complaint as a whole;
- C. That Defendant be awarded attorneys' fees and costs of suit as may be appropriate under applicable statutes;
- D. That the Court award Defendant such other relief as the Court may deem appropriate.

JURY DEMAND

Defendant demands a trial by jury on any of Plaintiff's claims triable to a jury.

1 **COUNTERCLAIM**

2 Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counterclaimant
3 Hologenix, LLC (“Hologenix”) states and alleges as follows:

4 **PARTIES, JURISDICTION AND VENUE**

5 1. Counterclaimant Hologenix is a Delaware limited liability company
6 that is headquartered in Santa Monica, California. Hologenix’s members are
7 citizens of California, Colorado, New York, Puerto Rico and the European Union.

8 2. Upon information and belief, Counter-Defendant Multiple Energy
9 Technologies, LLC (“MET”) is a Delaware limited liability company, having its
10 principal place of business at 470 Johnson Road, Suite 220, Meadow Pointe Plaza,
11 Washington, PA 15301 and domiciled in Pennsylvania.

12 3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331
13 and 15 U.S.C. § 1121.

14 4. This Court may properly exercise personal jurisdiction over MET
15 because MET has done business and entered into contracts in California, and MET
16 purposely availed itself of the laws of California by, among other things, filing the
17 underlying action in this district.

18 5. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because a
19 substantial part of the events or omissions giving rise to the claim occurred in this
20 District, and MET filed the underlying action in this District.

21 **FACTUAL ALLEGATIONS**

22 6. Hologenix manufactures, promotes and sells a bioceramic product
23 called Celliant™, which is a proprietary mineral matrix that can be embedded into
24 the core of a yarn or applied to a wide variety of fabrics.

25 7. Hologenix sells Celliant as both a powder and a fiber that can be
26 incorporated into a extensive range of products, including technical outerwear,
27 athletic wear, base layer, wetsuits, bedding, equestrian apparel, insulations,
28 veterinary products and furniture.

1 8. The FDA has determined that Celliant products are medical devices as
2 defined in section 201(h) of the Federal Food, Drug and Cosmetic Act and are
3 general wellness products. Celliant is also designated as a Class 1 Medical Device
4 in Canada, the European Union, Australia, and New Zealand.

5 9. Upon information and belief, MET manufactures, promotes and sells a
6 bioceramic powder branded as “Redwave™”.

7 10. Upon information and belief, MET also manufactures, promotes and
8 sells a bioceramic powder branded as “Biopower™”.

9 11. Upon information and belief, MET operates separate websites for the
10 Redwave and Biopower brands.

11 12. Upon information and belief, Redwave and Biopower are the same
12 product, just branded differently. Redwave and Biopower are collectively referred to
13 herein as the “MET Product.”

14 13. MET claims that the MET Product is based on Far Infrared
15 Technology (“FIR”).

16 **MET’s Deceptive and Misleading Claims**

17 14. Upon information and belief, MET is and has been operating an
18 Internet web site under the domain name <http://redwaveglobal.com> where it
19 advertises and offers the MET Product for sale to businesses and consumers.

20 15. Upon information and belief, MET is and has been operating an
21 Internet web site under the domain name <http://biopower-usa.com> where it
22 advertises and offers the MET Product for sale to businesses and consumers.

23 16. MET has attempted to differentiate the MET Product from other
24 bioceramics materials and products, like Celliant, through deceptive, false and
25 misleading statements about its products.

26 17. For example, MET makes the following claims about the MET
27 Product on the Redwave website at <https://redwaveglobal.com>:
28

- 1 a. Through meticulous lab work and experimentation, we took
- 2 what we already knew about FIR and some insights of our own
- 3 and fine-tuned it into a more powerful, more effective solution.
- 4 b. Our proprietary formula concentrates this power, delivering a
- 5 far more potent exposure to the FIR's therapeutic rays.
- 6 (last visited April 9, 2019).

7 18. Similarly, on the Biopower website, MET references the purported
8 Brazilian origin of the MET Product to imply the MET Product is superior to other
9 bioceramics:

10 The journey to establish BIOPOWER™ took us to the Amazon in
11 Brazil where we mined our core ingredient, bioceramics, that became
12 the foundation of our proprietary patent pending
13 formula. Bioceramics, often used in surgical implants, are ultra-
14 fine mineral particles that have the proven ability to reflect and emit
15 far infrared, enhancing the body's physiological recovery
16 process. MET further refines its bioceramics into a powder
17 preserving these compelling benefits. This supercharged powder can
18 then be incorporated into thousands of therapeutic delivery formats.

19 <http://biopower-usa.com/technology/#about-tech> (last visited April 9, 2019).

20 19. MET also claims that the MET Product uses a specialized “vibrational
21 technology” that enhances the effects of FIR:

22 BIOPOWER™ is an integrated technology engineered to harness the
23 powerful effects of far-Infrared enhanced by vibrational technology.

24 <http://biopower-usa.com/about/#about-us> (last visited April 9, 2019).

25 20. Despite making claims about the specialized nature of the MET
26 Product because of MET's proprietary formula, Brazilian-sourced bioceramic
27 material and “vibrational technology”, MET only supports these claims with
28 generalized science regarding FIR technology.

21 21. MET fails to offer any scientific support for its claims that the MET
22 Product is more potent than other bioceramics.

23 22. MET fails to offer any scientific support for its claims that the MET
24 Product is more potent or effective because it sources its bioceramics materials in
25 Brazil.

1 23. MET fails to offer any scientific support for its claims that “vibrational
2 technology” makes the MET Product more powerful.

3 24. MET’s representations and claims regarding the MET Product being
4 superior to other bioceramics products because of MET’s proprietary formula,
5 Brazilian-sourced bioceramic material and “vibrational technology”, are false and
6 misleading.

7 25. MET knew or should have known that its representations regarding the
8 MET Product being superior to other bioceramics products because of MET’s
9 proprietary formula, Brazilian-sourced bioceramic material and “vibrational
10 technology” were false and unsupported by any scientific evidence or studies.

11 26. MET’s claims regarding the MET Product being superior to other
12 bioceramic materials or products, like Celliant, because of MET’s proprietary
13 formula, Brazilian-sourced bioceramic material and “vibrational technology” are
14 misleading because they have a tendency to deceive a substantial segment of its
15 audience.

16 27. MET’s deception regarding the superiority of the MET Product to
17 other bioceramic materials and products, like Celliant, is material in that it is likely
18 to influence purchasing decisions by consumers and other interested in
19 manufacturing products using bioceramic materials like the MET Product or
20 Celliant.

21 28. MET caused its false statements regarding the MET Product being
22 superior to other bioceramic materials or products to enter interstate commerce by
23 publishing these statements on the Biopower and Redwave websites.

24 **MET’s Products are Unregistered and Unapproved Medical Devices**

25 29. MET has advertised and continues to advertise the claimed benefits of
26 the MET Products on the Redwave and Biopower websites.

1 30. Specifically, MET also makes a number of representations about the
2 MET Product's effect on physical and disease endpoints, which seek to create the
3 impression that the MET Products are effective at achieving these endpoints.

4 31. Specifically, MET states on Biopower's website that:

5 Products powered with BIOPOWER™ have the unique ability to help
6 improve biological functions. BIOPOWER™ is designed to help the
7 body restore itself and generate natural energy by increasing cellular
8 metabolism, inducing analgesia, promoting muscle relaxation, and
9 decreasing inflammation and oxidative stress.

10 <http://biopower-usa.com/about/> (last visited April 9, 2019).

11 32. MET also claims that the MET Product allows the body "to recover
12 and heal quicker." See <http://biopower-usa.com/technology/> (last visited April 9,
13 2019).

14 33. Additionally, MET claims on Redwave's website that the MET
15 Product is "for anyone looking for preventative measures to stay healthy." See
16 <https://redwaveglobal.com/> (last visited April 9, 2019).

17 34. Products which have an intended use to treat or prevent disease, and
18 which do not achieve their primary intended purposes through chemical action
19 within or on the body, and which are not dependent on being metabolized for the
20 achievement of their primary intended purposes, are medical devices under section
21 201(h) of the Federal Food, Drug, and Cosmetic Act (codified at 21 USC §
22 321(h)).

23 35. Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act,
24 device manufacturers that are not subject to Premarket Approval requirements must
25 notify FDA of their intent to market a medical device at least 90 days in advance.
26 This is known as Premarket Notification - also called PMN or 510(k).

27 36. A 510(k) is a premarket submission made to FDA to demonstrate that
28 the device to be marketed is at least as safe and effective, that is, substantially
equivalent, to a legally marketed device that is not subject to premarket approval.

1 37. A medical device cannot be marketed without some form of premarket
2 review by the FDA, known as a 510k clearance, unless the device is exempt from
3 review requirements.

4 38. MET did not obtain a 510k clearance for the MET Product.

5 39. MET's medical device is not exempt from 510k clearance
6 requirements.

7 40. Because the MET Product is a medical device based on MET's
8 representations about its efficacy in achieving certain physical and disease
9 endpoints and MET did not obtain a 510k clearance for the MET Product, it does
10 not comply with the FDA's medical device requirements.

11 41. MET knew or should have known that its claims regarding the efficacy
12 of the MET Product in achieving certain physical and disease endpoints were
13 misleading because it knew that the MET Product had not been approved as a
14 medical device by the FDA.

15 42. MET's claims regarding the efficacy of the MET Product in achieving
16 certain physical and disease endpoints were misleading because they have a
17 tendency to deceive a substantial segment of its audience into believing that the
18 MET Product was a medical device approved by the FDA.

19 43. MET's deception is material in that it is likely to influence purchasing
20 decisions by consumers and other interested in manufacturing products using
21 bioceramic materials like the MET Product or Celliant.

22 44. MET caused its false statements regarding the MET Product being a
23 medical device approved by the FDA to enter interstate commerce by publishing
24 these statements on the Biopower and Redwave websites.

MET Lacks Substantiation for its Claims

45. In addition to making health-related claims regarding the MET Product, which cannot be made absent FDA approval, MET also lacks adequate substantiation for these claims.

46. Even if MET's claims regarding the efficacy of the MET Product on disease were permissible by the FDA, the Federal Trade Commission ("FTC") requires adequate substantiation prior to using these, or any other, claims in marketing materials, including the Redwave and Biopower websites.

47. Upon information and belief, MET does not have sufficient scientific substantiation for its claims regarding the efficacy of the MET Product.

48. On the Biopower website, MET has made available six studies on the MET Product and one FIR literature review.

49. The MET Product studies are color-coded to associate each one with particular claims and indications, such as "analgesic," "anti-inflammatory," and "sports". This color coding necessarily suggests to the reader that the MET Product studies substantiate the identified claims and indications.

50. The MET Biopower studies are insufficient to substantiate MET's claims and indications for the MET Product.

51. On the Biopower website, MET identifies three studies as supporting its claims that the MET Product is "analgesic" and "anti-inflammatory." All three of these studies were conducted in mice or rats.

52. On the Biopower website, MET identifies three studies as supporting its claims that the MET Product provides a benefit with respect to "sports."

53. The studies that MET identified as supporting the MET Product's beneficial effects on people engaged in "sports" examine such endpoints as physical performance generally, balance, flexibility, grip strength, and respiratory capacity. All of these claims create a general impression that the MET Product offers benefits for people engaged in athletics, or even generally in vigorous physical activity.

1 54. Of the three studies that MET identifies as supporting the MET
2 Product's beneficial effects on people engaged in "sports" one of these is a rodent
3 study and two are human studies with extremely small sample sizes, one involving
4 17 subjects and one involving 9-12 subjects.

5 55. MET identifies all six studies as supporting the MET Product
6 generally.

7 56. Rodent studies are not competent and reliable scientific evidence to
8 substantiate claims for product benefits relating to human performance because
9 advertising and claims regulators (which include not only the FDA, but also the
10 FTC and state regulators) would not generally accept studies in rodents as sufficient
11 proof of behavior in humans.

12 57. Studies with extremely small sample sizes (thirty or less) are
13 insufficient, standing alone, to support claims about the benefits of the MET
14 Product for people engaged in athletics or other vigorous activity.

15 58. Moreover, one of the human study's used to support MET's claim that
16 the MET Product provided benefits for people engaged in athletics examined
17 benefit after 5 months of wear, while the other involved a period of "extended
18 wear" (i.e., 7 days/week throughout the day). These use patterns are not what
19 would be expected for a typical consumer purchasing athletic apparel and thus the
20 results are not conclusive for the general population.

21 59. Given the limitations on the sample sizes and study subjects, the six
22 studies MET identifies to support its claims regarding the benefits of the MET
23 Product on humans can only be considered illustrative, and must be viewed in
24 conjunction with the wide body of literature on FIR, generally, in order to
25 substantiate MET's claims regarding the MET Product.

26 60. MET makes numerous other claims about the benefits of the MET
27 Product for which it does not identify any supporting studies. For example, MET
28

1 does not identify any of the studies on its website as supporting MET's claims of
2 the efficacy of the MET Product on "healing" or "prevention."

3 61. Upon information and belief, there are no scientific studies that
4 support MET's claims of the efficacy of the MET Product on "healing" or
5 "prevention."

6 62. MET makes numerous claims that differentiate the MET Product from,
7 and imply the MET Product is superior to other bioceramics materials and products,
8 including Celliant. None of the studies available on the MET website compare the
9 MET Product to any other FIR products.

10 63. Upon information and belief, MET there is no evidence comparing the
11 characteristics of the MET Product to any other bioceramic materials or products.

12 64. Nonetheless, MET states on the Biopower website that:

13 "Well documented, tested and proven in numerous medical and scientific
14 publications, far infrared has been shown to support an increase in cellular
15 metabolism, fight inflammation, promote cell energy and reduce oxidative
16 stress. Ultimately, by working with you, BIOPOWER™ helps promote
17 recovery from life's daily activities, allowing the body to return to a healthy
18 state."

18 <http://biopower-usa.com/technology/#about-tech> (last visited April 10, 2019).

19 65. Reliance on the extensive scientific literature on FIR, generally, and
20 not on studies specifically examining the MET Product when compared to other
21 bioceramic materials or products, is insufficient to substantiate MET's claims that
22 there is anything unique or different about the MET Product in comparison with
23 Celliant or any other FIR or bioceramic technology.

24 66. At the time MET made the deceptive representations about the MET
25 Product, it knew or should have known that it did not have sufficient data to
26 substantiate these representations, making MET's representations deceptive and
27 misleading.
28

1 67. MET's false and misleading claims about the MET Product have been
2 repeated in the press and by physicians.

3 68. On November 21, 2017, an article was published on prnewswire.com
4 that repeated a number of the false and misleading statements about the MET
5 Product, including:

6 a. a statement by MET's Chair of its Technology Committee, Dr. Alan
7 Letton, which stated that "By harnessing the physiological benefits of
8 Far Infrared, we created therapeutic apparel able to improve health as
9 it's worn – making recovering from an all-out effort faster, easier, and
10 more efficient";

11 b. a statement by Dr. Vaugh McCall, who specializes in psychiatry and
12 health behavior at the Medical College of George, which stated "How
13 one sleeps at night affects focus, performance, and overall functioning
14 during the following day. Using Redwave's technology, this new line
15 works to restore the body, assuring you'll rest easy and wake up
16 refreshed."

17 [https://www.prnewswire.com/news-releases/redwave-global-announces-](https://www.prnewswire.com/news-releases/redwave-global-announces-partnership-with-under-armour-inc-300559537.html)
18 [partnership-with-under-armour-inc-300559537.html](https://www.prnewswire.com/news-releases/redwave-global-announces-partnership-with-under-armour-inc-300559537.html)

19 69. These statements were repeated in other media publications, including
20 in an article by Obi Anyanwu on fashionnetwork.com. See
21 [https://us.fashionnetwork.com/news/Under-Armour-partners-with-Redwave-for-](https://us.fashionnetwork.com/news/Under-Armour-partners-with-Redwave-for-sleepwear-collection,894050.html#.XK0rrlVKhEY)
22 [sleepwear-collection,894050.html#.XK0rrlVKhEY](https://us.fashionnetwork.com/news/Under-Armour-partners-with-Redwave-for-sleepwear-collection,894050.html#.XK0rrlVKhEY).

23 70. MET's claims regarding the MET Product being superior to other
24 bioceramic materials or products, like Celliant, based on general FIR research and
25 studies has a tendency to deceive a substantial segment of its audience.

26 71. MET's deception regarding scientific evidence of the superiority of the
27 MET Product to other bioceramic materials and products, like Celliant, is material
28 in that it is likely to influence purchasing decisions by consumers and other

1 interested in manufacturing products using bioceramic materials like the MET
2 Product or Celliant.

3 72. MET caused its false statements regarding the MET Product being
4 superior to other bioceramic materials or products to enter interstate commerce by
5 publishing these statements on the Biopower and Redwave websites.

6 73. MET and Hologenix are in direct competition with each other because
7 the MET Product and Celliant are comparable.

8 74. Upon information and belief, MET has realized and continues to
9 realize an unfair competitive advantage due to its use of false and deceptive
10 advertisements, which violates federal and state law.

COUNT I

(Violation of the Lanham Act (15 U.S.C. § 1125(a)(1)(B))

11
12
13 75. Plaintiff incorporates by reference the preceding paragraphs of this
14 Counterclaim as if fully set forth herein.

15 76. MET falsely and/or misleadingly represents facts related to the MET
16 Product to customers, potential customers, and members of the public.

17 77. MET's representations are literally false or are otherwise misleading
18 and deceptive and serve to disparage Hologenix's products.

19 78. Such representations of fact, undertaken in commercial advertising or
20 promotion, misrepresent the nature, characteristics, or qualities of Hologenix's and
21 MET's goods, services, and/or commercial activities and are false and misleading,
22 in that, for example, MET's representations give the impression that the MET
23 Product is more potent than Celliant, is approved by the FDA to treat certain
24 diseases and is substantiated by scientific studies.

25 79. MET's representations actually, or are likely to, deceive a substantial
26 segment of their intended audience of potential customers and customers of
27 bioceramic products, as well as the public.

1 80. MET's representations are material in their effects on the purchasing
2 decisions of potential customers and customers of bioceramic products. These
3 representations have influenced, and will continue to influence, purchasing
4 decisions of such customers and potential customers.

5 81. MET has caused its false and/or misleading advertisements and
6 representations to enter interstate commerce in that it provides the MET Product
7 nationwide and has published these false and/or misleading advertisements and
8 representations online.

9 82. MET's false and misleading representations are acts of false
10 advertising, product disparagement, and unfair competition in violation of the
11 Lanham Act.

12 83. The acts of MET have been committed with intent to cause confusion
13 and mistake, and with knowledge of their wrongful nature.

14 84. The false advertising, product disparagement, and unfair trade
15 practices by MET are intentional and willful.

16 85. As a direct and proximate result of MET's actions, Hologenix has been
17 and will continue to be severely injured in its business and property through lost
18 opportunities, profits, and otherwise, that would have been available to Hologenix
19 had MET accurately and truthfully represented the capabilities of the MET Product
20 and how the MET Product compares to Hologenix's products.

21 86. In addition to the injury to Hologenix, as a direct and proximate result
22 of MET's actions, the public has been and will continue to be harmed and
23 negatively affected in that it has and continues to receive false and/or misleading
24 information about the MET Product and how it compares to Hologenix's Products.

25 87. Hologenix is entitled to an injunction to prevent MET from continuing
26 to brazenly make the aforementioned false, misleading and unsubstantiated
27 representations, and to correct the false impression left by MET's deception.
28

88. Because this is an exceptional case involving calculated and willful misconduct by MET, Hologenix is entitled to recover up to three times the amount of actual damages and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Hologenix respectfully requests that the Court enter judgment in its favor as follows:

A. Preliminarily and permanently enjoining MET, its agents, representatives, employees, assigns, and all persons acting in concert or privity with it, from falsely advertising or making misleading and unsubstantiated representations related to the MET Product and how it compares to Hologenix's products, and other bioceramic products;

B. Issuing a permanent injunction ordering that MET, at its own expense, engage in appropriate corrective advertising designed to reach all persons to whom the false and misleading statements made by MET were directly or indirectly disseminated, and retracting the false and misleading statements previously made;

C. Awarding Hologenix monetary damages sufficient to compensate it for losses sustained on account of MET's unlawful conduct as alleged above;

D. Awarding Hologenix MET's profits derived by reason of the unlawful acts complained of, as provided by law;

E. Awarding Hologenix punitive and/or treble damages;

F. Awarding Hologenix reasonable attorneys' fees, prejudgment interest, and costs of this action as provided by law; and

G. Awarding Hologenix any other relief that the Court deems just and equitable.

Dated: April 12, 2019

POLSINELLI LLP

By: /s/ Noel Cohen
Noel S. Cohen
*Attorneys for Defendant and
Counterclaimant Hologenix, LLC.*

CERTIFICATE OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES:

At the time of service, I was over 18 years of age and not a party to this action. I am employed at Polsinelli LLP in the County of Los Angeles, State of California. My business address is 2049 Century Park East, Suite 2900, Los Angeles, California, 90067.

On April 12, 2019, I served true copies of the following document(s) described as

DEFENDANT'S ANSWER TO COMPLAINT AND COUNTERCLAIM

BY CM/ECF NOTICE OF ELECTRONIC FILING: I electronically filed the document(s) with the Clerk of the Court by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system. Participants in the case who are not registered CM/ECF users will be served by mail or by other means permitted by the court rules.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 12, 2019, at Los Angeles, California.

/s/ Jill Serena
Jill Serena